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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,976	12/29/2003	Anthony Joonkyoo Yun	PALO-004	8822

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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT	PAPER NUMBER
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3762

MAIL DATE	DELIVERY MODE
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12/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/748,976

Applicant(s)

YUN ET AL.

Examiner

Michael Kahelin

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 17-38 is/are pending in the application.
- 4a) Of the above claim(s) 12-14 and 21-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 17-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - a. A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
3. Claims 1, 4, 7, 9, 10, 17, 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rezai (US 2005/0065574, hereinafter "Rezai") in view of Verrier et al. (US 5,437,285, hereinafter "Verrier"). Please note that Examiner has confirmed "Table II" of Rezai's disclosure is supported by its presentation in PCT/US03/02847, which is currently unpublished.
4. In regards to claims 1, 17, and 18, Rezai discloses modulating a portion of the autonomic nervous system of a female subject known to suffer from a fertility condition.

Because the therapy is applied "to affect the hypothalamic-related condition" (par. 0006), and the hypothalamic-related conditions, including infertility and irregular/painful menses are listed in Table II, Rezai inherently discloses, "providing a female subject known to suffer from said fertility condition". Alternatively, it is well known to provide a patient having a pathological state with a particular therapy that is known to be an effective treatment for said pathological state to improve the wellbeing of the patient. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Rezai's method with the step of providing a female patient known to suffer from a fertility condition to effectively treat said fertility condition and to improve the wellbeing of the patient.

5. Further, Rezai's invention is capable of increasing the sympathetic activity/parasympathetic activity ratio of the subject, and is capable of treating a fertility condition (Table II, line 1 indicates "infertility" and "irregular/painful menses", which means the device is applied to a female). For evidence that hypothalamus stimulation will result in increasing the said ratio, please refer to US 4,339,384 (Maillard et al.), column 8, line 34. Additionally, any stimulation of the autonomic system that increases the ratio of sympathetic activity to parasympathetic activity will inherently treat a fertility condition. Further, Rezai discloses a closed-loop feedback mechanism (par. 0047) that will determine a variable (from the sensor) before, during, and after modulation because it is running in a loop fashion. Rezai does not disclose that the variable is the ratio of sympathetic activity to parasympathetic activity. Verrier teaches of an ANS sensing system wherein the ratio of sympathetic activity to parasympathetic activity (col. 7, line

21) is determined to sense the vulnerability of the organ innervated by the ANS (col. 6, line 3). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Rezai's invention by determining the ratio of sympathetic activity to parasympathetic activity to sense the vulnerability of the organ innervated by the ANS.

6. In regards to claims 4 and 10, the increase in the ratio comprises increasing sympathetic activity (see Maillard).

7. In regards to claim 7, the modulation is localized (Fig. 1).

8. In regards to claim 9, electrical energy is applied to the autonomic nervous system (abstract). Since the hypothalamus controls the autonomic nervous system, Examiner is interpreting the hypothalamus to be part of the ANS.

9. In regards to claim 20, the fertility condition is infertility (Table II, line 1).

10. Claims 2 and 3 are rejected under 35 U.S.C. 102(e) as anticipated by Rezai or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rezai in view of Bothe Loncar et al. (US 2002/0188336, hereinafter "Bothe"). Rezai discloses the essential features of the claimed invention, including providing stimulation continuously (par. 0042), which would inherently provide modulation during the luteal phase. Alternatively, Rezai does not explicitly specify performing modulation during the luteal phase of the menstrual cycle. Bothe teaches of providing ANS modulation during the luteal phase of the menstrual cycle (par. 0264) to enhance the functions of the specific phase where pregnancy occurs. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Rezai's invention by modulating the

ANS during the luteal phase to enhance the functions of the specific phase where pregnancy occurs.

11. Claims 5, 6 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rezai in view of Whitehurst et al. (US 6,832,114, hereinafter "Whitehurst"). Rezai discloses the essential features of the claimed invention except for modifying the ratio by decreasing parasympathetic activity or increasing sympathetic activity and decreasing parasympathetic activity. Whitehurst teaches of ANS modulation achieved by inhibiting parasympathetic stimulation and/or activating sympathetic stimulation (col. 18, line 60) to more accurately modulate the innervated organ. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Rezai's invention by providing ANS modulation by inhibiting parasympathetic stimulation and/or activating sympathetic stimulation to more accurately modulate the innervated organ.

12. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rezai in view of Mann et al. (US 2002/0055761, hereinafter "Mann"). Rezai discloses the essential features of the claimed invention except for stimulating the pelvic nerve. Mann teaches of stimulating a pelvic nerve (par. 0076) to more locally treat a fertility condition so as to not affect other systems of the body (abstract). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Rezai's invention by stimulating a pelvic nerve to more locally treat a fertility condition so as to not affect other systems of the body.

13. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rezai in view of Khan et al. (US 2002/0064501, hereinafter "Khan"). Rezai discloses the essential features of the claimed invention except for determining the ratio of Th1 to Th2. Khan teaches of regulating the Th1/Th2 ratio to facilitate fertility where improved implantation is required. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Rezai's invention by determining the ratio of Th1 to Th2 to further facilitate fertility.

Response to Arguments

14. Applicant's arguments filed 10/9/2007 have been fully considered but they are not persuasive. Applicant argued that Rezai discloses a lengthy list of conditions that are treated with the hypothalamus stimulation technique, but does not provide any further teaching of how the method is to be applied. However, Rezai discloses the stimulation technique to the level of detail of the claim language. As addressed above, the stimulation of the hypothalamus will "modulat[e] at least a portion of the autonomic nervous system...to increase the...ratio." Regardless of whether Rezai discloses specific signal parameters or more in-depth description of the stimulation method; the claim language does not require such detail.

15. Applicant further argued that Verrier only discloses determining the sympatho-vagal balance of an individual with a heart condition. However, Rezai teaches of a closed-loop system to control the autonomic stimulation for treating a fertility condition (pars. 0047-48). The feedback for this loop is disclosed as being one or more of several

nervous system parameters (including vagal or autonomic), such as "the rate and pattern of neuronal activity." *Id.* Verrier is relied upon only for the well-known teaching that sympathetic/parasympathetic balance is one such "pattern of neuronal activity" that is used as a feedback mechanism of autonomic influence for stimulators; see also Schuler et al. (US 2006/0224189). Accordingly, the claimed invention is the application of a known technique to a known device ready for improvement to yield predictable results, thus obvious.

Conclusion

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

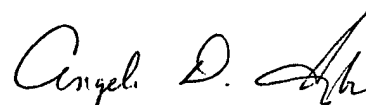
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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12/12/07

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